REMARKS

The Office Action mailed November 26, 2002, has been received and reviewed. Claim 16 having been cancelled, claim 8 having been amended, the pending claims in the above-identitied application are claims 1-15 and 17-20. Of these, claims 5-13 are under examination. Reconsideration and withdrawal of the rejections are respectfully requested.

Objection to Claim 16

The Examiner objected to claim 16 as depending from a nonelected claim. In order to expeditite prosecution of the above-identified application, Applicant has cancelled claim 16 thereby rendering the Examiner's objection moot. Withdrawal of the objection to claim 16 is respectfully requested.

Rejection Under 35 U.S.C. §101

Claims 8-13 and 16 were rejected under 35 U.S.C. §101 as allegedly not being supported by either a specific and substantial credible utility or a well established one. In rejecting the claims, the Examiner stated that "the specification fials to provide specific support . . . such as information about a functional activity, biological significance of zcytor14 polypeptide, or any known ligand for the putative cytokine receptor of the instant invention" (page 3 of the Office Action). This rejection is respectfully traversed.

Applicant respectfully submits that the rejection is contrary to both the law and the United States Patent Office's own examination guidelines. The application of these standards to biotechnology inventions is discussed in the January 5, 2001 Federal Register Notice of the United States Patent Office's Utility Examination Guidelines. Section II.B.1(c)(1) and (2) of the January 5, 2001 "Utility Examination Guidelines" states "[a]n invention has a well-established utility if a person of ordinary skill would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties...), and the utility is specific, substantial, and credible" (66 FR 4, p. 1098). Moreover, "[a] patent examiner must accept a utility asserted by an applicant unless the Examiner has sound scientific reasoning to rebut the

assertion" (66 FR 4, p. 1096). To establish a *prima facie* showing of lack of utility, "the Office must ... provide a sufficient evidentiary basis for factual assumptions relied upon in establishing the *prima facie* showing ... the PTO must do more than merely question operability - it must set forth factual reasons which would lead one of skill in the art to question the objective truth of the statement of operability" (MPEP 2107.02(IV)). In addition, 66 FR 4, p. 1096 states that:

> When a class of proteins is defined such that the members share a specific, substantial, and credible utility, the reasonable assignment of a new protein to the class of sufficiently conserved proteins would impute the same specific, substantial, and credible utility to the assigned protein. . . . [A] 'rigorous correlation' need not be shown in order to establish practical utility; 'reasonable correlation' is sufficient.

Upon reading the specification, one of skill in the art would appreciate that zcytor14 is a member of the sufficiently conserved Interleukin-17 receptor related family of proteins and would reasonably impute that same specific, substantial, and credible utility to zctyor14.

The Examiner has provided no evidence or scientific basis to refute the assertions of utility for the polynucleotides of the present invention. The invention indeed has a specific asserted and a well-established utility for the claimed polynucleotides that are supported by the specification. Thus, Applicant submits that the Examiner has not established a *prima facie* showing of lack of utility, because it has not provided sound scientific reasoning to rebut the assertion of utility in the application and the evidence presented by Applicant therein. In view of the Examiner's apparent failure to note and evaluate this evidence, Applicant submits that a *prima facie* showing of no specific and substantial credible utility has not been made.

For the above reasons, Applicant respectfully submits that the invention recited in claims 8-13 and 16 is useful. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §101 are respectfully requested.

Rejection Under 35 U.S.C. §112, First Paragraph

Claims 8-13 and 16 were rejected under 35 U.S.C. §112, first paragraph, "since the claimed invention is not supported by either a specific, substantial or credible utility . . ., one skilled in the art clearly would not know how to use the claimed invention" (page 4 of the Office Action). This rejection is respectfully traversed.

As discussed above, Applicant has indeed asserted a specific and well established utility for the inventions recited in claims 8-13 and 16. Claims 8-13 and 16 are indeed supported by a specific utility that is substantial and credible. Moreover, upon reading the specification, one of skill in the art would know how to make and use the isolated nucleic acid molecule (claim 8), the vector (claim 9), the expression vector (claim 10), the recombinant virus (claim 11), the recombinant host cell (claim 12), and the method of using the expression of claim 10 to produce a protein (claim 13) without undue experimentation. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph, are respectfully requested.

Summary

On the basis of the above amendments and remarks, Applicant believes that each rejection has been addressed and overcome. Reconsideration of the application and its allowance are respectfully requested. If for any reason the Examiner feels that a telephone conference would expedite prosecution of the application, the Examiner is invited to telephone the undersigned at (206) 442-6540.

Respectfully Submitted,

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Enclosures:
Petition and Fee for Extension of Time (in duplicate)
Amendment Fee Transmittal (in duplicate)
Postcard